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PHYSICIANS FOR SOCIAL RESPONSIBILITY®
1101 Fourteenth Street Northwest Suite 700 Washington DC 20005

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telephone (202) 898-0150
facsimile (202) 898-0172
email: psrnatl@psr.org
internet: www.psr.org

May 9, 1999

Dockets Management Branch (HFA-305),
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

On behalf of over 15,000 doctors and health professionals who are members of Physicians for Social Responsibility, I thank you for the opportunity to comment on the need for federal regulations that require irradiated food to be labeled as such. As physicians, we practice the principle of prior informed consent with patients. A similar principle should guide the government on food labeling. Because studies have shown that food irradiation depletes the vitamin content of food, it is important that consumers know what they are purchasing and eating. Other effects of the irradiation process are not fully known, but potentially include added toxics in our food supply and increased dangers from transportation and handling of radiation sources.

Prominent labeling on irradiated foods is essential. If irradiation statements on food products are not prominent, but instead less conspicuously displayed in a list of ingredients, consumers will regard irradiation as a thoroughly researched safe process with little or no possible health consequences. They will also assume the process is sanctioned by the FDA, the agency responsible for insuring Americans have safe and nutritious food.

There is evidence that irradiated foods lose vitamin content, particularly vitamins A, C, E and some B complex vitamins. Evidence also shows that cooking irradiated foods may cause an additional inordinate loss of nutrients. The FDA currently allows the food supply to be irradiated at extremely high doses. The intensities allowed for treating spices, pork, and fresh fruits and vegetables are millions of times greater that the intensity of a normal chest x-ray. The amount of vitamin loss varies from one type of food to another, but in general there is a direct relationship between the amount of irradiation and the extent of nutritional value lost.

While irradiation does not make food radioactive, there is concern that foods processed by irradiation may contain radiolytic products that could have toxic and carcinogenic effects. The irradiation process produces unique radiolytic products whose chemical and toxic properties have not been characterized. More research is needed to identify the chemical properties of these radiolytic products before a risk of cancer is discounted. Until substantial research is available showing that these radiolytic products are benign, consumers should have the benefit of prominently displayed information regarding whether their food is treated with radiation.

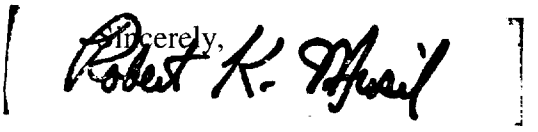
The source of the radiation used is either cobalt 60 or cesium 137. If irradiation facilities multiply due to increased radiation treatment, storage, transportation and handling of these dangerous substances will also increase. Because there are insufficient regulations covering food irradiation facilities and poorly developed local management plans dealing with transportation accidents, these processes pose a potential increased danger to workers in radiation plants and to the general public.

In the interest of prior informed consent, the public should be:

- made aware of the possible health repercussions of eating irradiated foods and,
- clearly informed of which foods are treated with radiation by prominent placement of this information on food packaging.

At this time there is insufficient data on the increased toxicity and the decreased nutritional value of irradiated foods. Therefore, it is essential that information informing consumers that their food has been treated with radiation remain prominent and obvious on foods and food packaging.

Sincerely,



Robert K. Musil, Ph.D.
Executive Director

enc.: PSR Resolution on The Use of Food Irradiation in the Prevention of Food Borne Illness.

THE USE OF FOOD IRRADIATION IN THE PREVENTION OF FOOD BORN ILLNESS

Physicians for Social Responsibility,

Acknowledging that disease caused by food born illness causes thousands of deaths and millions of episodes of diarrheal illness in the United States each year and that infection with E Coli 0157:H7 caused four deaths and over 700 cases in the Northeast United States and required recall of contaminated ground beef from suppliers (1,2,3).

Recognizing that the Food and Drug Administration, the Department of Agriculture and the Department of Health and Human Services have responded to these events by implementing new and expanded performance-based requirements and standards for sanitation and microbial testing in the food industries and that these programs including the Hazard Analysis and Critical Control Point system are believed by food safety experts to be an appropriate response to the threat of food born illness (2,4).

Believing that the biggest threat of food born illness comes from the growing importation of foods that are not subject to U.S. standards of packaging, handling and inspection, a situation that will require the promotion of global food safety standards through the World Trade Organization and regional free trade arrangements (3).

Further recognizing that food irradiation is presently being promoted by many agencies of government, industry and academia as an acceptable treatment of meat, poultry, fruit, vegetables, and spices for bacterial decontamination, retardation of spoilage and pest control and acknowledging that while such irradiation of food does not make the food radioactive, it may affect the nutritional adequacy of the foods. (5,6,8,11)

Understanding that while radiation is efficacious in killing bacteria and other pathogens in laboratory settings there is no available evidence that the large scale commercial irradiation of the U.S. food supply will reduce the incidence of food born illness in the general population and that projects must be designed and conducted to demonstrate the effectiveness of food irradiation (5,6,7).

Noting that food irradiation uses extremely high doses of gamma or electron radiation, less than one to over 10 Kilograys or 100,000 to several million rads, (one gray is 100 rads.) that one chest xray is on the order of 20mrad and the radiation LD50 for humans is 6-900 rads and noting further that there are no well established facility safety designs or emergency medical management plans or procedures to prevent or manage accidents in such high radiation environments (8,9.10).

Believing that the design and conditions of use of food irradiation facilities are not adequately regulated and inspected by the U.S. Nuclear Regulatory Commission and the Food and Drug Administration, and that radiation protection standards devised for nuclear power plant operations are not appropriate for application to food irradiation facilities and that new and specific standards and procedures for food irradiator operations must be developed (11,12).

Believing that the hazards to workers in the operation of a large scale widespread food irradiation industry are essentially unknown and noting that food irradiation exposure chambers operate in air at ambient temperature and pressure and that the high radiation flux during each exposure produces high concentrations of ozone which must be vented at the end of each cycle before the chamber can be opened and that worker and community exposure to this ozone is unstudied (8).

Understanding that the Implementation of a large scale food irradiation program with hundreds of facilities will involve the manufacture and transportation of highly radioactive cobalt or cesium sources and subsequent radioactive waste on roadways through U.S. Communities and that accidents in such transport are inevitable, that local emergency management plans are poorly developed, that federal regulations of such transport have not dealt with food irradiation sources (8, 12).

Understanding further that cesium and cobalt radiation sources must be manufactured in large scale and that the fabrication of cesium sources would likely require the large scale reprocessing of nuclear fuel rods, a highly toxic and dangerous process now not conducted commercially in the United States since the late 195O's (8,18).

Believing that there is a growing pressure from the nuclear and food industries to implement commercial food irradiation of large fractions of the U.S. food supply on a nationwide basis using arguments of low cost and safety reminiscent of the early days of growth of the nuclear power industry (electricity too cheap to meter) when major issues of occupational and public health are unresolved and issues of societal cost and effectiveness of a new industry are unstudied (14,15,16)

Therefore Physicians for Social Responsibility:

1. Does not, at this time, support the commercial use of irradiation technologies for purposes of food sterilization or food spoilage control or the development of a commercial food irradiation industry,

2. Urges appropriate federal and private agencies to assess the implications for worker safety of present plans and designs for high volume commercial food irradiators with particular attention to radiation safety in environments of extremely high radiation fluxes and to worker and community exposures to irradiatior produced ozone release,

3. Urges appropriate federal and private agencies to conduct thorough policy research to determine the cost, safety, insurance and liability, public health and safety and consumer choice and acceptance dimensions of a large scale nationwide commercial food irradiation industry

4. Urges federal and private agencies to develop and refine non radiation technologies and procedures to assure the safety of the U.S. food supply including the negotiation of appropriate standards of food safety in international trade agreements.

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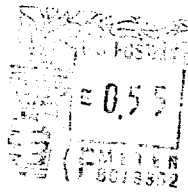

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